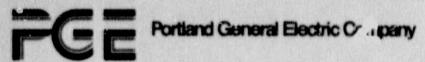
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FAR (48 CFR) 53.243



James E. Cross Vice President, Nuclear

September 17, 1990

Trojan Wuclear Plant Docket 50-344 License NPF-1

U.S. Nuclear Regulatory Commission Attn: Decument Control Desk Washington DC 20555

Dear Sirs:

## Fitness for Duty

Attached please fird a report describing an incident concerning unsatisfactory performance testing that occurred as part of the Trojan Nuclear Plant Fitness for Luty program. The report is submitted in accordance with the requirements of Title 10, Code of Federal Regulations, Part 26, Appendix A. The incident involved the contract drug testing laboratory reporting a certified positive blind performance test specimen as being negative.

Sincerely.

Attachment

c: Mr. John B. Martin Regional Administrator, Region V U.S. Nuclear Regulatory Commission

> Mr. David Stewart-Smith State of Oregon Department of Energy

Mr. R. C. Barr NRC Resident Inspector Trojan Nuclear Plant

NRC-26-87-420 Modification No. 11 Page 2 of 2

The purpose of this modification is to add incremental funds in the amount of \$120,000.00. Accordingly, the contract is modified as follows:

Paragraph B.2, "Consideration and Obligation", subparagraph c, is revised as follows:

"c. The amount presently obligated by the Government with respect to this contract is \$2,630,000.00."

All other terms and conditions, including the ceiling amount of \$2,824,401.16, shall remain the same.

Trojan Nuclear Plant Docket 50-344 License NFF-1 Document Control Desk September 17, 1990 Attachment Page 1 of 3

### REPORT OF UNSATISFACTORY PERFORMANCE TESTING BY CONTRACT DRUG TESTING LABORATORY

## Description of Occurrence

On August 14, 1990, a shipment of 22 specimens was sent to Portland General Electric Commany's (PGE's) contract drug testing laboratory for analysis. The 22 specimens included 17 random, 3 pre-access, and 2 blind specimens. One blind spiked specimen was certified to contain 52 ng/ml phencyclidine (PCP) for which PGE tests at an initial and confirmatory screening level of 25 ng/ml.

On August 17, 1990, the contract laboratory incorrectly reported the PCP specimen as negative to PGE's Medical Review Officer (MRO). On that same date, PGE's Medical Technologist informed the laboratory of the incident of false negative reporting. The laboratory was requested to investigate the circumstances and to perform reanalysis by gas chromatography/mass spectrometry (GC/MS). In addition, the laboratory was requested to review all quality control data associated with confirmatory testing of that particular specimen.

Also, on August 17 the contract laboratory ascertained that the sample in question was screened on the evening of August 14 and found to be positive for PCP. The confirmation test procedures that were commenced on the morning of August 15 resulted in no PCP being detected by GC/MS.

On August 21, 1990, PGE's Fitness For Duty (FFD) program submitted an additional PCP specimen certified to be identical in concentration to the specimen in question. On August 24, 1990, the laboratory correctly reported the results of this specimen as positive to PGE's MRO.

#### Cause of Occurrence

Review of PGE's contract laboratory's investigative report of the incident indicates that the false negative report was the result of an administrative error at the laboratory. The factors that led to this conclusion are as follows:

- Repeat analysis of the sample in question by the contract laboratory resulted in PCP being detected at r level above PGE's citoff level for PCP.
- Confirmation test logs document that an aliquot of Sample Number 814:1417 was used for confirmation testing instead of an aliquot from the sample in question, Sample Number 814:1471.

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It was also noted from the investigative report that, even though the erroneous sample number was documented, the certifying scientist failed to detect the discrepancy. Furthermore, the zero response on the GC/MS and yes was not investigated relative to the initial positive screening result.

#### Corrective Actions

The following steps will be taken by the contract laboratory:

- An internal incident report will be completed to document the individual responsible for the administrative error, why it occurred, and what steps need to be taken to prevent its recurrence.
- The procedure for certifying scientist review of test results will be modified to include a specific instruction to check accession number and sample number on the Confirmation Chain of Custody against the work sheet and the Custody and Control Form. All certifying scientists will be informed and instructed of this change.
- 3. An additional review step will be included for all specimens that initially screen positive but for which the confirmatory GC/MS response is zero. This review will be performed by either the Scientific Director or one of the toxicology supervisors.

The above actions will be complete by October 17, 1990. In addition, PCE's Medical Technologist will conduct an onsite audit of the contract laboratory's accessioning and certifying process within the next 30 days, which will include verification of the laboratory's corrective actions.

#### Significance of Occurrence

This event did not affect Plant safety nor security. The incident involved a spiked test specimen. Genuine samples submitted to the laboratory at the same time were deemed to be correctly interpreted and reported. The screening problem was identified by PGE's FFD Quality Assurance Program. Blind test specimens are routinely submitted to the laboratory to ensure integrity of the testing and reporting process. PGE has a high level of confidence in this laboratory's performance. This incident is the first occurrence of an administrative error by this laboratory.

As cf August 17, 1990, PGE's FFD program had submitted 611 blind specimens to this laboratory. PGE's false negative rate is 1.9 percent which is well within industry established acceptability ranges for laboratory performance.

No press releases have been made nor are any contemplated by PGE.

Trojan Nuclear Plant Docket 50-344 License NPF-1 Document Control Desk September 17, 1990 Attachment

# Previous Similar Events

Since the implementation of PGE's FFD program on January 3, 4%, this is the third occurrence of false negative reporting of a known positive quality control specimen at this laboratory. It is also the fifth occurrence of false negative reporting by PGE. Each event has involved a different metabolite and/or a unique set of circumstances specific to the respective specimen. One earlier event, which occurred on February 28, 1990 at another contract laboratory, was also determined to be caused by an administrative error. The drug was detected but reported as negative because the cutoff level applied by the technologist was incorrectly set at a value higher than PGE's cutoff level. These two administrative error occurrences, each by a different laboratory, are deemed to be unrelated and do not constitute a trend.

PGN/bsh 5016W.0990